

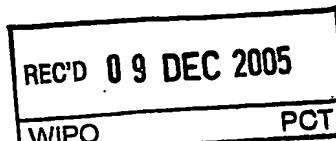
PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY



(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)



Applicant's or agent's file reference GN-22588-PCT	FOR FURTHER ACTION See Form PCT/IPEA/416	
International application No. PCT/KR2004/001940	International filing date(day/month/year) 02 AUGUST 2004 (02.08.2004)	Priority date (day/month/year) 05 AUGUST 2003 (05.08.2003)
International Patent Classification (IPC) or national classification and IPC IPC7 C12Q 1/68		
Applicant KIM, Cheol-Min et al		

- This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.
- This REPORT consists of a total of 5 sheets, including this cover sheet.
- This report is also accompanied by ANNEXES, comprising:
 - ☐ (sent to the applicant and to the International Bureau) a total of _____ sheets, as follows:
 - ☐ sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).
 - ☐ sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.
 - ☐ (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) _____, containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box relating to Sequence Listing (see Section 802 of the Administrative Instructions).
- This report contains indications relating to the following items:
 - ☒ Box No. I Basis of the report
 - ☐ Box No. II Priority
 - ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
 - ☐ Box No. IV Lack of unity of invention
 - ☒ Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
 - ☐ Box No. VI Certain documents cited
 - ☐ Box No. VII Certain defects in the international application
 - ☐ Box No. VIII Certain observations on the international application

Date of submission of the demand 03 MARCH 2005 (03.03.2005)	Date of completion of this report 23 NOVEMBER 2005 (23.11.2005)
Name and mailing address of the IPEA/KR  Korean Intellectual Property Office 920 Dunsan-dong, Seo-gu, Daejeon 302-701, Republic of Korea Facsimile No. 82-42-472-7140	Authorized officer CHO, YOUNG GYUN Telephone No. 82-42-481-8132 

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/KR2004/001940

Box No. I Basis of the report

1. With regard to the language, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.

- ☒ This report is based on translations from the original language into the following language English, which is the language of a translation furnished for the purposes of:
- ☐ international search (under Rules 12.3 and 23.1(b))
 - ☒ publication of the international application (under Rule 12.4)
 - ☐ international preliminary examination (under Rules 55.2 and/or 55.3)

2. With regard to the elements of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

- ☒ the international application as originally filed/furnished

- ☐ the description:
- pages _____ as originally filed/furnished
- pages* _____ received by this Authority on _____
- pages* _____ received by this Authority on _____

- ☐ the claims:
- pages _____ as originally filed/furnished
- pages* _____ as amended (together with any statement) under Article 19
- pages* _____ received by this Authority on _____
- pages* _____ received by this Authority on _____

- ☐ the drawings:
- pages _____ as originally filed/furnished
- pages* _____ received by this Authority on _____
- pages* _____ received by this Authority on _____

- ☒ the sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing.

3. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages _____
- ☐ the claims, Nos. _____
- ☐ the drawings, sheets _____
- ☐ the sequence listing (*specify*): _____
- ☐ any table(s) related to sequence listing (*specify*): _____

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

- ☐ the description, pages _____
- ☐ the claims, Nos. _____
- ☐ the drawings, sheets _____
- ☐ the sequence listing (*specify*): _____
- ☐ any table(s) related to sequence listing (*specify*): _____

* If item 4 applies, some or all of those sheets may be marked "superseded."

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/KR2004/001940

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	5-14, 16-18	YES
	Claims	1-4, 15	NO
Inventive step (IS)	Claims	5-14, 16-18	YES
	Claims	None	NO
Industrial applicability (IA)	Claims	1-18	YES
	Claims	None	NO

2. Citations and explanations (Rule 70.7)

The following documents have been considered for the purpose of this report:

D1: Zhonghua Gan Zang Bing Za Zhi, Vol. 11(6), pp. 361-363 (JUNE 2003)

D2: WO 2001/004358 (INNOGENETICS N.V.) 28 JANUARY 2001

D1 discloses oligonucleotide microarray, which is used for detecting resistance gene against lamivudine from hepatitis B virus (HBV) infected patients.

D2 discloses a method and a diagnostic kit for the monitoring of antiviral drug resistance in a patient by genetic detection of at least one of the mutations in the DNA polymerase of the HBV strains present in a biological sample of said patient.

I. Novelty & Inventive Step

1) Claims 1-4 & 15

Claims 1-4 of the present invention relate to a microarray with target probes for detecting drug-resistance HBV on a support, wherein the target probes comprise oligonucleotides having nucleotide sequences that can specifically bind to a target gene inducing resistance to lamivudine and/or famciclovir. Claim 15 relates to a HBV diagnostic kit comprising the microarray of any one of claims 1-13.

D1 and D2 disclose a microarray for detecting the mutations of resistance gene to lamivudine and/or famciclovir from HBV infected patients. The subject matter of claims 1-4 and 15 is not distinguishable from the disclosure of D1-D2.

Therefore, claims 1-4 and 15 in this invention are not considered to be novel under PCT Article 33(2).

(Continued on Supplemental Sheet.)

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

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Supplemental Box Relating to Sequence Listing

Continuation of Box No. I, item 2:

1. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this report was established on the basis of:

a. type of material



a sequence listing



table(s) related to the sequence listing

b. format of material



in written format



in computer readable form

c. time of filing/furnishing



contained in the international application as filed



filed together with the international application in computer readable form



furnished subsequently to this Authority for the purposes of search and/or examination



received by this Authority as an amendment* on _____

2. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed of furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

3. Additional comments:

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.
Continuation of:

Box No. V

2) Claims 5-14 & 16-18

Claims 5-14 relate to a microarray with target probes for detecting drug-resistance HBV on a support, wherein the target probes comprise oligonucleotides including nucleotide sequences of point mutations at 528, 529 and 514 in domain B and at 552, 548 and 555 in domain C of HBV DNA polymerase gene inducing resistance to lamivudine and/or oligonucleotides including nucleotide sequences of point mutations at 528 and 529 in domain B and at 555 in domain C of HBV DNA polymerase gene inducing resistance to famciclovir, in particular, oligonucleotides including the nucleotide sequences of SEQ ID NOs 7-47; and the use of said microarray. Claim 16 relates to a primer or probe for detecting HBV drug resistance comprising one of nucleotide sequences of SEQ ID NOs 1-47. Claims 17-18 relate to a negative control probe having one of nucleotide sequences of SEQ ID NOs 48-73.

However, none of the prior art documents discloses target probes comprising oligonucleotides including the nucleotide sequences of SEQ ID NOs 7-47. Thus, said target probes would not have been obvious to a person skilled in the art from the disclosure of D1-D2.

Therefore, claims 5-14 and 16-18 meet the requirements of novelty and inventive step under PCT Article 33(2) and 33(3).

II. Industrial Applicability

The subject matter of claims 1-18 is considered to be industrially applicable under Article 33(4). //